RESEARCH PAPER

DEVELOPMENT AND EVALUATION OF TASTE-MASKED MOUTH DISSOLVING TABLETS OF LEVOCETIRIZINE HCL

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Received: 25th May, 2026; **Revised:** 6th June, 2026; **Accepted:** 8th June, 2026; **Available Online:** 09th June, 2026

ABSTRACT

Levocetirizine Hydrochloride is a potent third-generation antihistaminic agent widely prescribed for the treatment of allergic rhinitis, chronic idiopathic urticaria, and other allergic disorders. Despite its therapeutic effectiveness, the intensely bitter taste of the drug often leads to poor patient compliance, particularly among pediatric and geriatric populations. The present study was aimed at developing and optimizing taste-masked mouth dissolving tablets (MDTs) of Levocetirizine Hydrochloride using Tulsion 335 ion-exchange resin technology.

Taste masking was achieved by preparing a drug-resin complex through ion-exchange interactions between Levocetirizine Hydrochloride and Tulsion 335. Preliminary optimization studies were conducted to evaluate the effects of swelling time, stirring time, and drug-to-resin ratio on drug loading efficiency and taste masking performance. A 2^3 full factorial design was employed to optimize the formulation variables. The optimized drug-resin complex was subsequently incorporated into MDT formulations containing various superdisintegrants including Sodium Starch Glycolate, Croscarmellose Sodium, Crospovidone, and Kyron T-314.

The prepared formulations were evaluated for pre-compression parameters, post-compression characteristics, drug content, wetting time, disintegration time, dissolution behavior, and stability. Among the factorial design batches, batch A8 exhibited the highest drug loading and complete taste masking. The optimized MDT formulation B23 containing Crospovidone demonstrated satisfactory hardness, low friability, rapid wetting time, short disintegration time, and excellent dissolution performance. Stability studies confirmed that the optimized formulation remained stable under accelerated storage conditions.

The study concluded that Tulsion 335 effectively masked the bitter taste of Levocetirizine Hydrochloride without affecting drug release characteristics. The optimized MDT formulation exhibited rapid disintegration, acceptable mechanical properties, enhanced patient acceptability, and potential for improved therapeutic compliance. The developed formulation represents a promising patient-friendly dosage form for pediatric and geriatric patients suffering from allergic disorders.

Keywords: Levocetirizine Hydrochloride; Mouth Dissolving Tablets; Taste Masking; Tulsion 335; Ion Exchange Resin; Crospovidone; Orodispersible Tablets; Fast Dissolving Tablets; Factorial Design; Superdisintegrants; Drug-Resin Complex; Patient Compliance.
How to cite this article: Saraswat P, Jat YS, Kumar R. Development and Evaluation of Taste-Masked Mouth Dissolving Tablets of Levocetirizine HCl. Int J Drug Deliv Technol. 2026;16(57s): 1953-1963. DOI: 10.25258/ijddt.16.57s.198

Source of support: Nil.

Conflict of interest: None.

Introduction

Oral drug delivery remains the most preferred route of drug administration because of its convenience, ease of administration, cost-effectiveness, and high patient compliance [1]. Conventional oral dosage forms such as tablets and capsules are widely accepted; however, these dosage forms may create difficulties for pediatric, geriatric, and dysphagic patients who experience swallowing problems [2,3].

To overcome these limitations, Mouth Dissolving Tablets (MDTs), also known as Orodispersible Tablets (ODTs), have been developed as patient-friendly dosage forms capable of rapidly disintegrating in the oral cavity without the need for water [4]. MDTs provide several advantages, including rapid onset of action, improved patient compliance, convenience during administration, and enhanced bioavailability due to pregastric absorption [5,6].

The demand for MDTs has increased significantly over the past two decades because these formulations improve medication adherence among pediatric and elderly patients [7]. Several technologies such as freeze drying, spray drying, sublimation, direct compression, and melt granulation have been employed in the development of MDTs [8]. Among these approaches, direct compression is considered one of the most economical and convenient methods due to its simplicity and suitability for large-scale manufacturing [9].

One of the major challenges associated with MDT formulation is the unpleasant taste of active pharmaceutical ingredients. Since MDTs disintegrate directly in the oral cavity, the drug comes into immediate contact with taste buds, resulting in bitterness and poor patient acceptability [10]. Therefore, effective taste masking is considered an essential prerequisite for successful MDT development [11].

Various taste-masking approaches have been investigated, including polymer coating, microencapsulation, inclusion complexation, adsorption, granulation, molecular complexation, and ion-exchange resin technology [12,13]. Among these methods, ion- exchange resin technology has gained considerable attention because it offers excellent taste masking efficiency, simplicity of processing, safety, and compatibility with conventional tablet manufacturing processes [14].

Ion-exchange resins are water-insoluble polymers containing ionizable functional groups capable of exchanging ions with surrounding media [15]. These resins form stable complexes with oppositely charged drug molecules through ionic interactions. The resulting drug-resin complexes remain stable in saliva but dissociate in gastric fluid due to the presence of competing ions, thereby releasing the drug for absorption [16].

Levocetirizine Hydrochloride is a potent third-generation antihistaminic agent widely prescribed for seasonal allergic rhinitis, perennial allergic rhinitis, and chronic idiopathic urticaria [17]. Levocetirizine is the active R-enantiomer of cetirizine and demonstrates approximately two-fold greater affinity for H1 receptors than cetirizine [18]. Due to its high receptor selectivity, the drug provides effective relief from allergic symptoms while producing minimal sedative effects [19].

Despite its therapeutic effectiveness, Levocetirizine Hydrochloride possesses an intensely bitter taste that significantly affects patient compliance, particularly in pediatric and geriatric populations [20]. Therefore, successful development of MDTs requires efficient taste masking while maintaining rapid disintegration and satisfactory drug release characteristics [21].

Tulsion 335, a weak acid cation-exchange resin, has been extensively investigated for pharmaceutical taste-masking applications because of its excellent ion-exchange capacity, chemical stability, and pharmaceutical acceptability [22]. Previous studies have demonstrated that Tulsion 335 effectively masks the bitterness of various cationic drugs while maintaining rapid drug release under gastric conditions [23,24].

Optimization of pharmaceutical formulations is commonly achieved using Design of Experiments (DoE) methodologies. Factorial design represents a systematic statistical approach that enables simultaneous evaluation of multiple formulation variables and their interactions [25]. A 2^3 full factorial design is particularly useful for investigating the influence of three independent variables at two levels while minimizing experimental runs [26].

In the present investigation, swelling time, stirring time, and drug-to-resin ratio were selected as independent variables for optimization of the drug-resin complex. The optimized complex was subsequently formulated into MDTs using different super disintegrants including Sodium Starch Glycolate, Croscarmellose Sodium, Crospovidone, and Kyron T-314 [27].

Super disintegrants are essential excipients that facilitate rapid tablet disintegration through swelling, capillary action, deformation recovery, and particle repulsion mechanisms [28]. Their incorporation significantly reduces disintegration time and improves dissolution behavior of MDTs [29].

Therefore, the present study was undertaken to develop and optimize taste-masked mouth dissolving tablets of Levocetirizine Hydrochloride

using Tulsion 335 ion-exchange resin and suitable super disintegrants. The study aimed to achieve efficient taste masking, rapid disintegration, acceptable mechanical strength, and enhanced patient compliance through formulation optimization using a 2^3 factorial design approach [30].

1. Materials and Methods

1.1 Materials

Levocetirizine Hydrochloride was obtained as a gift sample from a reputed pharmaceutical manufacturer and used as the model drug for the present investigation. Tulsion 335, a weak acid cation-exchange resin, was employed as the taste-masking agent. Sodium Starch Glycolate (SSG), Croscarmellose Sodium (CCS), Crospovidone, and Kyron T-314 were used as super disintegrants. Mannitol was used as a diluent due to its pleasant mouthfeel and cooling sensation, while Microcrystalline Cellulose PH-102 served as a directly compressible filler. Talc and Magnesium Stearate were used as glidant and lubricant, respectively. All chemicals and reagents utilized in this study were of analytical grade [31].

1.2 Pre formulation Studies

1.2.1 Organoleptic Evaluation

Levocetirizine Hydrochloride was evaluated for color, odor, appearance, and taste. The drug was found to be a white crystalline powder with a characteristic intensely bitter taste, which necessitated the application of taste-masking technology [32].

1.2.2 Determination of λ max

The absorption maximum of Levocetirizine Hydrochloride was determined using UV-Visible Spectrophotometry. A stock solution was prepared in distilled water and scanned between 200–400 nm. The maximum absorbance was observed at 231 nm and selected for further analytical studies [33].

1.2.3 Preparation of Calibration Curve

A calibration curve was prepared by analyzing standard solutions of Levocetirizine Hydrochloride at different concentrations. Absorbance was measured at 231 nm and plotted against concentration. The method exhibited linearity within the selected concentration range and complied with Beer-Lambert's law [34].

1.3 Drug–Excipient Compatibility Studies

Compatibility studies were performed to evaluate possible interactions between Levocetirizine Hydrochloride and excipients used in formulation development.

1.3.1 Fourier Transform Infrared Spectroscopy (FTIR)

FTIR spectroscopy was employed to investigate potential interactions between the drug and excipients. Samples of pure drug, resin, and optimized drug-resin complex were analyzed using the potassium bromide pellet method over a scanning range of 4000–400 cm^{-1} [35].

1.3.2 Interpretation of FTIR Spectra

The characteristic peaks of Levocetirizine Hydrochloride were compared with those of the optimized formulation. Retention of principal peaks confirmed the absence of significant chemical interactions and demonstrated compatibility between the drug and formulation components [36].

1.4 Taste Masking by Ion-Exchange Resin Technology

Ion-exchange resin technology was selected as the taste-masking approach because of its simplicity, safety, and effectiveness in masking bitter drugs [37]. Tulsion 335, a weak acid cation-exchange resin, was chosen owing to its high exchange capacity and pharmaceutical acceptability.

The drug-resin complex was formed through ionic interaction between positively charged Levocetirizine molecules and negatively charged functional groups present on the resin matrix. Such complexes remain stable in saliva but dissociate under gastric conditions due to the presence of competing ions, thereby releasing the drug for absorption [38].

1.5 Preparation of Drug–Resin Complex

The drug-resin complex was prepared by the batch process method. Predetermined quantities of Tulsion 335 were dispersed in distilled water and allowed to swell. Levocetirizine Hydrochloride was subsequently added and the mixture was stirred continuously for a specified period to facilitate ion exchange. The resulting complex was filtered, washed to remove unbound drug, dried, and stored for further evaluation [39].

1.6 Preliminary Optimization Studies

Preliminary optimization studies were conducted to identify critical factors influencing drug loading and taste masking efficiency. The influence of swelling time, stirring time, and drug- to-resin ratio was investigated systematically. Drug loading and taste masking efficiency were selected as response variables because they directly affect formulation performance [40].

1.7 Optimization Using 2^3 Full Factorial Design

A 2^3 full factorial design was employed to optimize the preparation conditions of the drug-resin complex. Factorial design is a powerful statistical tool that allows simultaneous evaluation of multiple variables and their interactions while minimizing the number of experimental runs [41].

Independent Variables			
Factor Variable	Low Level (-1)	High Level (+1)	
X1	Swelling Time	30 min	60 min
X2	Stirring Time	120 min	240 min
X3	Drug:Resin Ratio	1:3	1:6

Dependent Variables

- Y_1 = Percentage Drug Loading
- Y_2 = Taste Masking Efficiency

Eight experimental batches (A1–A8) were prepared according to the factorial design matrix. Statistical analysis was performed using regression equations and ANOVA to determine the significance of factors and their interactions [42].

1.8 Evaluation of Drug–Resin Complex

1.8.1 Percentage Drug Loading

Drug loading efficiency was determined by extracting the drug from the complex and estimating drug content spectrophotometrically at 231 nm. Percentage drug loading was calculated using a standard equation [43].

1.8.2 Taste Evaluation

Taste masking efficiency was evaluated by a panel of healthy volunteers using a bitterness rating scale. The effectiveness of taste masking was categorized as bitter, moderately masked, or completely masked [44].

1.8.3 In-Vitro Dissolution Study

Dissolution studies were performed using USP Dissolution Apparatus II (Paddle Method) with 900 mL dissolution medium maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically [45].

1.9 Formulation of Mouth Dissolving Tablets

The optimized drug-resin complex equivalent to 5 mg Levocetirizine Hydrochloride was selected for formulation of MDTs by direct compression. Various superdisintegrants including Sodium Starch Glycolate, Crospovidone, Croscarmellose Sodium, and Kyron T-314 were incorporated at different concentrations to optimize tablet performance [46].

1.10 Evaluation of Powder Blend

Before compression, powder blends were evaluated for flow properties including bulk density, tapped density, angle of repose, Carr's Index, and Hausner ratio according to standard pharmacopeial procedures [47].

1.11 Evaluation of Mouth Dissolving Tablets

Prepared MDTs were evaluated for:

- Weight variation
- Thickness
- Hardness
- Friability
- Drug content
- Wetting time
- Water absorption ratio
- In-vitro disintegration time
- In-vitro dissolution profile

All evaluations were performed according to standard pharmacopeial methods and reported procedures for orally disintegrating tablets [48].

1.12 Stability Studies

The optimized formulation (B23) was subjected to accelerated stability testing according to International Council for Harmonisation (ICH) guidelines. Samples were stored under refrigerated, elevated temperature, and accelerated conditions and evaluated periodically for changes in drug content, disintegration time, wetting time, and dissolution behavior [49].

1.13 Statistical Analysis

Experimental data obtained from factorial design studies were analyzed using multiple linear regression and analysis of variance (ANOVA). Mathematical models were generated to establish relationships between formulation variables and responses. Statistical significance was evaluated at a confidence level of 95%, and optimized formulations were selected based on maximum drug loading, effective taste masking, rapid disintegration, and satisfactory dissolution performance [50].

2. RESULTS AND DISCUSSION

2.1 Preformulation Studies

Preformulation studies were conducted to evaluate the physicochemical properties of Levocetirizine Hydrochloride and establish a suitable analytical method for quantitative estimation. The drug was identified as a white crystalline powder possessing an intensely bitter taste, which justified the necessity for taste masking prior to formulation into mouth dissolving tablets (MDTs) [51].

The UV spectrophotometric method developed for the estimation of Levocetirizine Hydrochloride exhibited maximum absorbance (λmax) at 231 nm in distilled water. The calibration curve demonstrated excellent linearity within the selected concentration range, confirming the suitability of the analytical method for subsequent studies [52].

2.2 FTIR Compatibility Studies

Fourier Transform Infrared Spectroscopy (FTIR) was employed to investigate possible interactions between Levocetirizine Hydrochloride and formulation excipients.

The FTIR spectrum of pure Levocetirizine Hydrochloride showed characteristic peaks corresponding to aromatic C-H stretching, carboxylic acid groups, and amine functionalities. Similar peaks were retained in the optimized drug-

resin complex and tablet formulation, indicating the absence of significant chemical interactions [53].

The retention of characteristic peaks confirmed that complex formation occurred through ionic interactions rather than chemical modification of the drug molecule. Therefore, Tulsion 335 and other excipients used in the study were considered compatible with Levocetirizine Hydrochloride [54].

Figure 1. FTIR Compatibility Study

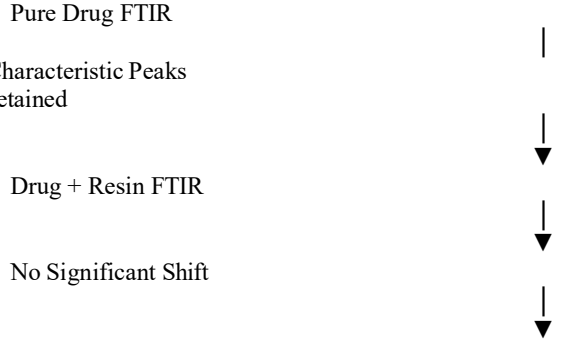

Figure 1: Schematic representation of FTIR compatibility study showing retention of characteristic peaks in the optimized formulation.

2.3 Optimization of Drug–Resin Complex

2.3.1 Preliminary Optimization

The influence of swelling time, stirring time, and drug-to-resin ratio on drug loading and taste masking was evaluated during preliminary optimization studies.

An increase in swelling time resulted in greater hydration of the resin matrix and improved accessibility of ion-exchange sites. Similarly, prolonged stirring enhanced drug diffusion into resin particles, leading to increased complex formation [55].

Drug loading was found to increase with increasing drug-to-resin ratio due to greater availability of exchangeable functional groups. Preliminary optimization studies identified batch F11 as the most promising formulation, exhibiting maximum drug loading and complete taste masking [56].

2.4 Optimization Using 2^3 Full Factorial Design

A 2^3 full factorial design was employed to optimize the preparation of the drug-resin complex. Swelling time (X_1), stirring time (X_2), and drug-to-resin ratio (X_3) were selected as independent variables, whereas percentage drug loading and taste masking efficiency were selected as dependent variables [57].

Table 1. Independent Variables Used in Factorial Design

Factor	Variable	Low Level (-1)	High Level (+1)
X_1	Swelling Time	30 min	60 min
X_2	Stirring Time	120 min	240 min
X_3	Drug:Resin Ratio	1:3	1:6

Table 2. Taste Masking Efficiency of Factorial Batches

Batch	Taste Masking
A1	+
A2	+
A3	++
A4	++
A5	+++

A6	+++
A7	+++
A8	+++

(+ = Bitter Taste, ++ = Moderate Taste Masking, +++ = Complete Taste Masking)

Among the factorial design batches, formulations A1–A4 exhibited comparatively lower drug loading and incomplete taste masking. In contrast, batches A5–A8 demonstrated complete taste masking, confirming successful formation of drug-resin complexes [58].

Batch A8 showed the highest percentage drug loading and complete taste masking and was therefore selected as the optimized formulation for further tablet development [59].

Figure 2. Influence of Formulation Variables on Drug Loading

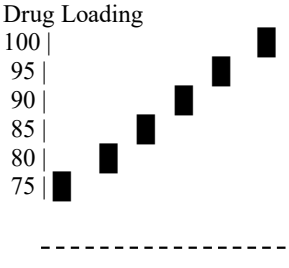

Figure 2: Graphical representation of increasing drug loading among factorial design batches.

2.5 In-Vitro Dissolution Study of Optimized Drug–Resin Complex

The dissolution profile of optimized batch A8 was compared with that of pure Levocetirizine Hydrochloride.

Table 3.

Dissolution Profile of Optimized Batch A8 Time (Min)	**% Drug Release**
0	0.00
5	74.65
10	78.99
15	83.32
20	87.81
25	92.35
30	96.73
45	100.40

The optimized drug-resin complex demonstrated complete drug release within 45 minutes. These findings indicate that complexation with Tulsion 335 did not adversely affect drug release characteristics [60].

Comparison of dissolution profiles revealed no significant difference between pure drug and optimized drug-resin complex, confirming that taste masking was achieved without compromising therapeutic performance [61].

Figure 3. Dissolution Profile of Optimized Batch A8

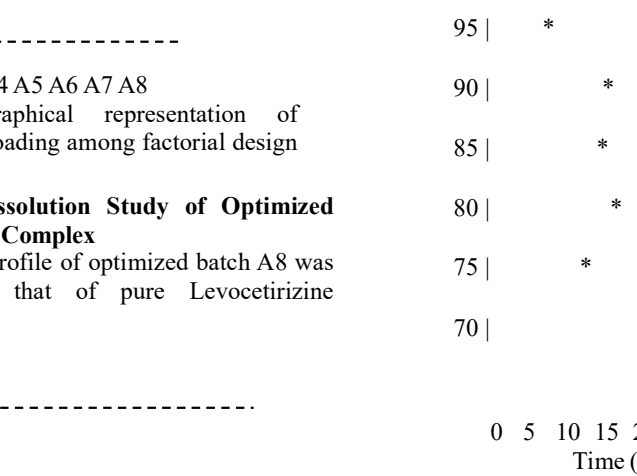

Figure 3: Dissolution profile of optimized batch A8 showing complete drug release within 45 minutes.

2.6 Statistical Analysis of Factorial Design

Regression analysis and ANOVA were performed to evaluate the effects of formulation variables on percentage drug loading.

The mathematical model generated for percentage drug loading was:

$$Y = B_0 + B_1X_1 + B_2X_2 + B_3X_3 + B_{12}X_1X_2 + B_{13}X_1X_3 + B_{23}X_2X_3 + B_{123}X_1X_2X_3$$

The positive coefficients obtained for swelling time, stirring time, and drug-to-resin ratio indicated that these variables exerted a favorable influence on drug loading efficiency [62].

The regression coefficient ($R^2 \approx 1$) demonstrated excellent agreement between observed and

predicted values, indicating high reliability of the optimization model [63].

The checkpoint batch prepared under optimized conditions produced experimental values close to predicted values, thereby validating the factorial design model [64].

2.7 Evaluation of Powder Blend

Flow properties of powder blends were evaluated before compression.

Table 4. Flow Properties of Powder Blend

Batch	Bulk Density	Tapped Density	Angle of Repose
B19	0.509	0.611	30.24
B20	0.517	0.612	31.25
B21	0.514	0.611	30.75
B22	0.524	0.621	32.12
B23	0.531	0.628	31.07

The angle of repose ranged from 26.18° to 33.21°, indicating acceptable flow properties suitable for direct compression [65].

Carr's Index values ranged from 14.61% to 16.69%, while Hausner ratios varied between 1.17 and 1.20, confirming good flowability and compressibility of the powder blends [66].

2.8 Evaluation of Mouth Dissolving Tablets

All formulations complied with pharmacopeial requirements for hardness, friability, drug content, and weight variation.

Among all formulations, batch B23 exhibited superior tablet characteristics.

Table 5. Evaluation of Optimized MDT Batch B23

Parameter	Value
Drug Content (%)	100.02
Hardness (kg/cm²)	2.5–3.5
Friability (%)	<0.5
Wetting Time (Sec)	26
Disintegration Time (Sec)	28

The rapid disintegration observed in batch B23 may be attributed to the high capillary activity and swelling behavior of Crospovidone, which promotes rapid penetration of saliva into the tablet matrix [67].

Figure 4. Wetting Time and Disintegration Time of Optimized Batch B23

Figure 4: Comparison of wetting time and disintegration time of optimized MDT formulation B23.

2.9 In-Vitro Dissolution Study of MDT Formulations

Dissolution studies demonstrated rapid drug release from all MDT formulations.

The optimized batch B23 released approximately 78% of drug within the first 5 minutes and achieved almost complete release within 20–25 minutes [68].

The enhanced dissolution behavior can be attributed to:

1. Efficient taste masking by Tulsion 335.
2. Rapid disintegration of tablets.
3. High wicking capacity of Crospovidone.
4. Increased surface area available for dissolution.

These factors collectively contributed to superior dissolution performance and improved drug availability [69].

Figure 5. Comparative Dissolution Profile of MDT Formulations

Figure 5: Representative dissolution profile showing rapid release from optimized batch B23.

2.10 Stability Studies

The optimized formulation B23 was subjected to accelerated stability studies according to ICH

guidelines [70].

6. Stability Parameters of Optimized Batch B23

Parameter	Initial	After 1 Month
Drug Content (%)	100.02	99.34
Wetting Time (Sec)	29.1	30.5
Disintegration Time (Sec)	25.3	26.6

The observed changes in formulation parameters during storage were negligible and remained within acceptable limits [71].

No significant alteration in dissolution behavior was observed after storage, indicating satisfactory stability of the optimized formulation [72].

Figure 6. Stability Profile of Optimized Batch B23

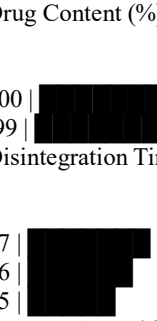

Figure 6: Stability profile of optimized MDT formulation B23 after storage.

2.11 Overall Discussion

The present investigation successfully demonstrated the utility of ion-exchange resin technology for taste masking of Levocetirizine Hydrochloride. Tulsion 335 effectively masked the bitter taste while preserving drug release characteristics [73].

Optimization studies confirmed that swelling time, stirring time, and drug-to-resin ratio significantly influence drug loading and taste masking efficiency [74].

Batch A8 was identified as the optimized drug-resin complex due to maximum drug loading and complete taste masking [75]. Furthermore, batch B23 emerged as the optimized MDT formulation owing to rapid disintegration, acceptable mechanical strength, superior dissolution profile, and satisfactory stability [76].

Overall, the developed formulation fulfilled all objectives of the study and demonstrated significant potential as a patient-friendly dosage form for pediatric and geriatric populations suffering from allergic disorders [77].

3. Conclusion

The present investigation successfully developed and optimized taste-masked mouth dissolving tablets (MDTs) of Levocetirizine Hydrochloride using Tulsion 335 ion-exchange resin technology. The bitter taste of Levocetirizine Hydrochloride was effectively masked through the formation of a drug-resin complex, thereby enhancing patient acceptability and compliance.

Optimization studies revealed that swelling time, stirring time, and drug-to-resin ratio significantly influenced drug loading and taste masking efficiency. The optimized drug-resin complex (Batch A8) exhibited complete taste masking, maximum drug loading, and satisfactory dissolution characteristics. Dissolution studies confirmed that complexation with Tulsion 335 did not adversely affect drug release behavior.

The optimized drug-resin complex was successfully incorporated into MDT formulations using various superdisintegrants. Among all formulations, Batch B23 demonstrated superior tablet characteristics, including acceptable hardness, low friability, rapid wetting time, short disintegration time, and excellent dissolution performance. Stability studies confirmed that the optimized formulation remained stable under accelerated storage conditions.

Overall, the developed MDT formulation successfully achieved the objectives of effective taste masking, rapid disintegration, satisfactory mechanical strength, and enhanced patient compliance. The formulation may provide a patient-friendly alternative for the management of allergic disorders, particularly among pediatric and geriatric populations.

4. Future Scope

1. The developed formulation may be evaluated through in-vivo pharmacokinetic studies to establish bioavailability and therapeutic performance.
2. Scale-up studies can be conducted to assess industrial feasibility and commercial manufacturing potential.
3. Alternative ion-exchange resins may be investigated to further improve taste masking efficiency and drug loading capacity.
4. The formulation approach may be extended to other bitter antihistaminic drugs and pediatric medications.
5. Long-term stability studies according to ICH guidelines may be performed to establish shelf-life.
6. Patient acceptability studies involving larger volunteer populations may be conducted to validate palatability and compliance.

Acknowledgement

The authors express sincere gratitude to the

School of Pharmacy, Raffles University, Neemrana, Rajasthan, India, for providing the necessary facilities, laboratory infrastructure, and academic support required for the successful completion of this research work.

The authors are also thankful to the faculty members, laboratory staff, and colleagues who contributed directly or indirectly to this study.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this research work.

Funding

The present research work did not receive any specific grant from funding agencies in the public, commercial, or non-profit sectors.

Data Availability Statement

The data generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Ethical Statement

Taste evaluation studies involving human volunteers were conducted following informed consent procedures and in accordance with institutional ethical considerations.References-

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